

# EXTENSIONS OF REMARKS

## PRESERVING PATIENT ACCESS TO METERED DOSE INHALERS

**HON. CHRISTOPHER H. SMITH**

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. SMITH of New Jersey. Mr. Speaker, today Mr. CLIFF STEARNS, my good friend from Florida, and I are introducing legislation aimed at helping those who suffer from respiratory conditions, particularly children with asthma, and preserve their access to medicines they rely upon to breathe—metered dose inhalers (MDI's).

Our legislation calls upon the Food and Drug Administration [FDA] and the Environmental Protection Agency [EPA] to delay their plans to remove chlorofluorocarbon-based MDIs from the marketplace before 2005. The resolution implores the FDA to continue to allow these critically important medicines to remain on the market while environmentally safe alternatives are developed and manufactured.

As many of you know, nearly 30 million Americans suffer from respiratory diseases of one kind or another, including asthma, chronic obstructive pulmonary disease [COPD], and cystic fibrosis. When the symptoms of these diseases strike, patients reach for the safe, effective, and proven medication delivery systems that have kept them alive for years—metered dose inhalers. Quite literally, metered dose inhalers enable patients to breathe freely and often mean the difference between life and death.

These inhalers are generally powered by chlorofluorocarbon [CFC] propellants. Under the 1987 Montreal Protocol, CFC's are to be phased out globally because of the damage they are believed to cause to the ozone layer. I believe it is important to point out, however, that the signatories to this Protocol explicitly recognized that certain uses of CFC's—such as MDI's—pose relatively small environmental risk yet generate tremendous health and safety benefits, and consequently, MDIs were given a temporary Essential-Use exemption from the treaty.

Despite this global exemption and the internationally recognized health benefits of MDI's, the U.S. FDA has unilaterally decided to accelerate the phase-out of CFC containing metered dose inhalers. Under the proposed framework, CFC containing inhalers—used safely and regularly by millions of asthmatic children, adults, and senior citizens—would be banned and consumers would be forced to purchase alternative products, even if there was but a single alternative on the market. I believe that this proposal is outrageous and totally unwarranted at this time.

Although pharmaceutical companies are working diligently to develop CFC-free MDI's, the FDA proposal will force patients to abandon their existing medications and could place them at the mercy of a single supplier in certain cases. This is fatally flawed in two important respects: first, each patient is unique and responds differently to asthma medication—even to the same medication—so the one-size-fits-all approach that FDA is pursuing will

harm many of these patients; and second, consumers will be charged higher prices due to the lack of competition in alternative MDI products.

Mr. Speaker, it is a well known fact that asthma is currently the No. 1 reason for school absences, and that roughly 5,000 Americans die each year from asthma-related complications. Furthermore, for millions of asthma sufferers, the single most important part of successful treatment is maintaining a steady medication routine. Disrupting this routine, which is a certain byproduct of the FDA's proposal, will needlessly put the lives and health of our children and senior citizens at risk.

I am also dismayed that the FDA, by seeking to ban CFC MDI's even when only a single alternative MDI is on the market, is making the erroneous assumption that all significant patient subpopulations—such as children and the elderly—will be equally served by the alternative product. This assumption is not only incorrect, but it violates the FDA's very own procedures and rules. All products that wish to obtain a pediatric indication must be reviewed separately by the FDA to determine whether the effect of a drug on children is the same as an adult. Yet, in its zeal to phase out CFC products before the United States is even required to do so, the FDA is trampling on this principle.

An additionally egregious aspect of the FDA's proposed rule is that it is an answer in search of a problem. The United States is in absolutely no danger of missing the Montreal Protocol's compliance deadline (2005) for completely eliminating CFC's, and there is no need to abruptly ban MDI's that have been widely and safely used for years.

Furthermore, the amount of CFC's used in metered dose inhalers is so small—less than 0.025 kg per inhaler—that the marginal environmental improvement in the ozone layer that would result from the FDA plan would be virtually undetectable.

To put these amounts into perspective, consider that in 1996, transitional stockpiles of CFC's for use in air conditioners and refrigeration equipment totaled between 36,000 and 72,000 tons. The total production of CFC's used for MDI's that year was only 2,600 tons, and MDI's are responsible for less than 1 percent of the risk to the ozone layer, as measured by atmospheric chlorine levels.

In addition, while the United States and developing countries must eliminate all CFC's by 2005, developing nations can continue to produce CFC's until 2010. Unless the FDA drastically modifies or delays its plan, asthma patients in the United States will have their dependable and effective medications taken away from them while consumers in China and Indonesia continue to use CFC's in hair spray and cosmetics.

It seems incomprehensible that anybody could support a proposal that secures negligible environmental benefits at a very steep cost to human lives and health. Notwithstanding, the FDA continues to move forward with its plan despite overwhelmingly negative public comments. I understand that the magnitude

of the public reaction to the FDA's advance notice was among the greatest—in terms of the numbers of letters received—in recent history. This is even more remarkable considering that the ban on metered dose inhalers has received very little media coverage.

In conclusion, Mr. Speaker, let me say there is no doubt that pharmaceutical companies should be encouraged by the FDA to develop, test, and bring alternative products to market before 2005. However, it is absurd and downright dangerous to put asthma patients—including children whose very lives depend on adhering to familiar medical routines—at risk by pulling effective and safe products from our shelves in order to meet a self-imposed standard. There is absolutely no reason to disrupt the lives of asthma and cystic fibrosis patients in the manner FDA has proposed. That is why I have joined my friend Congressman STEARNS in introducing this resolution today.

The alternative approach that we suggest to the FDA is very straightforward: allow the existing products—proven safe and effective over years of use—to be used until 2005, and encourage the development and use of alternative [CFC-free] metered dose inhalers so that asthma patients can gradually become accustomed to the different medications without undue disruptions and risks. Rather than forcing patients to switch medications suddenly and involuntarily, our approach would allow environmentally safe products to flourish and attain widespread acceptance.

I call upon my colleagues on both sides of the aisle to reject the FDA's cold turkey policy—Australia has already rejected that strategy. The United States can achieve its goal of zeroing out CFC production in 2005 without the heavy-handed, one-size-fits-all approach that the FDA has proposed. The children and senior citizens who depend on metered dose inhalers to breathe and live normal lives surely deserve better than that.

## TRIBUTE TO JACKIE O'CONNOR DOLLAR

**HON. FRANK RIGGS**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. RIGGS. Mr. Speaker, I rise today to commend the activities of Jackie O'Connor Dollar, the director of the Head Start Program in Napa and Solano Counties, which I represent. Last week, Jackie was presented with the Head Start-Johnson & Johnson Excellence in Management Award for her outstanding work on behalf of Napa and Solano Counties' children.

In September 1995, the Napa and Solano County Head Start programs were consolidated into one. Although this merger increased her area of responsibility by 400 percent, Jackie handled the change in stride and

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Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.

went ahead with her plans to begin new programs in the Heat Start classroom.

One of her most notable accomplishments is the implementation of an inclusive school project in which preschool children with severe disabilities are integrated with regular classroom students. By working closely with the county education offices and unified school districts, 90 students who would have normally attended classes for severely mentally and physically disabled children were, for the first time, to join mainstream classes.

I have personally visited the sites that Jackie has set up and have been impressed time and again with her hard work and commitment to the education of children with special needs.

Programs like Head Start work because of people like Jackie O'Connor Dollar. Her hard work, innovation, and accomplishments on behalf of northern California's children should be held up as a model for others.

TRIBUTE TO PETER C.  
CAMPANELLI, PSY.D.

**HON. EDOLPHUS TOWNS**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. TOWNS. Mr. Speaker, Mr. Peter Campanelli provides vital clinical services to individuals afflicted with mental illness. In his capacity as president and chief executive officer for the Institute for Community Living, Inc. [ICL], he is confronted with a difficult task.

He has organized and directed a private not-for-profit corporation for the purpose of development and operation of community residences for the mentally ill within the catchment areas of two large State psychiatric hospitals. ICL currently provides approximately 560 residential beds within various levels of care. Truly, Dr. Campanelli provides vital services to a constituency desperate for health and social services.

Dr. Campanelli's career of commitment and dedication is exemplary. He combines his passion with pragmatism. Additionally, he passes on the breadth and depth of his experience through the process of teaching in the university environment. It is my distinct pleasure to introduce him to my House colleagues.

TRIBUTE TO THE REVEREND  
WILLIE T. BARROW WELLNESS  
MEDICAL CENTER

**HON. BOBBY L. RUSH**

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. RUSH. Mr. Speaker, I rise to honor the Reverend Willie T. Barrow Wellness Medical Center of the Doctor's Hospital of Hyde Park that is being dedicated today in Chicago, IL. Originally founded in 1916 as the Illinois Central Railroad Hospital, the Doctor's Hospital of Hyde Park proudly serves more than 7,000 patients a month with a range of comprehensive community health services. And today, the hospital officially names The Wellness Center in honor of an electrifying community and spiritual leader, Dr. Willie T. Barrow, chairwoman of Operation PUSH.

The dedication of the Reverend Willie T. Barrow Wellness Medical Center marks a victory for residents of the first congressional district and the south side of Chicago. As the health care industry grows more complex and costly, and community hospitals are shuttered, it is vital that poor and working people, the very young and the very old, continue to have access to quality, preventive health care. And in a community where the infant mortality rate soars above 20, this is critical.

The hospital and the center are models of what community health care should be. Open 7 days a week, the hospital serves all in need. People without insurance, walk-ins, the homeless—all walk through the doors and receive quality care by a hard-working, well-trained staff.

The hospital and center are truly committed to the community. When the Hyde Park Community Hospital faced financial difficulties a few years ago, the leadership and perseverance of Dr. James H. Desnick assured that the hospital remained in the community, preserving more than 500 jobs and preserving health care services for residents.

Today, Dr. Desnick and the community officially name the Wellness Center in honor of Rev. Willie T. Barrow. Reverend Barrow exemplifies dedication in her life's work. As chairwoman of Operation PUSH, a founder of the Coalition of Labor Union Women, copastor of Mount Vernon Church of God in Chicago, and a long-time resident of the south shore community, Reverend Barrow truly serves the people. And in Chicago, she will be long remembered for her tireless work to elect Harold Washington, Chicago's first African-American mayor. Her commitment to human rights, civil rights, women's rights, and workers' rights inspires people across the Nation and across the globe.

As Congressman of the first congressional district, I send my heartiest congratulations to Dr. Desnick, the hospital board, the Community Advisory Board, and the 700 staff members, on the occasion of the dedication of the Reverend Willie T. Barrow Wellness Medical Center.

I am honored to represent the district that is home to the Reverend Willie T. Barrow Wellness Medical Center and to my good friend, Rev. Willie T. Barrow. And I pledge to continue my fight both in Congress and the city of Chicago to protect the survival of health programs like the center that promise to be a model for comprehensive community health care for people in need.

I am proud to offer these words of congratulations.

TRIBUTE TO LOLETA, CA, ON ITS  
CENTENNIAL

**HON. FRANK RIGGS**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. RIGGS. Mr. Speaker, I rise to celebrate the centennial of the beautiful community of Loleta in Humboldt County, CA, which I am privileged to represent.

I visited Loleta, which overlooks the picturesque Eel River Valley, just 2 weeks ago. The origin of its name is credited to the Wiyot Indians of the valley as a name for a pleasant

landmark. In this case, we are told, a quiet slough.

A.J. Doolittle made a map of Humboldt County in 1860, and it was adopted by the Humboldt County Board of Supervisors. There was no Loleta then, nor much of anything else. But from the gentle slope of the last of the foothills now occupied by today's Loleta, the map shows a nearby road from Dungan's Ferry, past W.J. Wing's, W. Ellery's, T.H. Foss', to L.H. Hawk's, en route to J.A. Sawyer's on Table Bluff.

An old Humboldt County Great Register for 1888 indicates Samuel Swauger, a 59-year-old native of Pennsylvania, ranching on what is now Loleta and registered to vote the previous year.

The late historian M.A. Parry, who wrote his masters thesis at Humboldt State University on Loleta, said Eel River & Eureka Railroad built Swauger's Station, now Loleta, in 1886. "From 1884 to 1886 the station amounted to no more than an uncovered loading platform standing beside a short length of track," he wrote. In 1898, as traffic increased, a new and larger depot was constructed. Swauger Station had been on the old structure, while "Loleta" appeared on the new.

Parry had this to say about the name of Swauger and Loleta: "In 1897, a faction of the community not satisfied with the name of the town, settled on 'Loleta' as what they wanted in place of 'Swauger's Station.' The word was of Indian origin and was said to mean 'pleasant place.' Actually it was three Indian words, 'Lo-le-tah,' meaning, 'pleasant place at the end of the water.' Loleta was just that; a pleasant place at the end of Hawk's Slough which no longer extends so far inland."

By adopting Loleta as the town name, the community did no more than adopt the name the community's Indians had used for years. The name became official in February 1897 when Will Perrott filed a map with the county recorder entitled "Loleta—Amended Map of Swauger's." The railroad company and the post office followed suit the following year.

And now, beautiful Loleta, famous for its fine dairy farms and livestock ranches, prepares for the centennial celebration. I congratulate Robert Laffranchi, president of the Loleta Chamber of Commerce, and all the people of Loleta for what I'm sure will be a wonderful day of festivities.

TRIBUTE TO YASHPAL ARYA, M.D.

**HON. EDOLPHUS TOWNS**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, July 9, 1997*

Mr. TOWNS. Mr. Speaker, I rise today to recognize Dr. Yashpal Arya. Dr. Arya is chief of gastroenterology/endoscopy at Wyckoff Heights Medical Center. He has worked at Wyckoff since 1976.

Born in India, and medically trained in his homeland, Dr. Arya has established an impressive portfolio of professional achievements. He is a member of numerous committees and organizations, including the American College of Gastroenterology, the New York State Medical Society, and the Queens Medical Society. Additionally, he has been the recipient of the Isadore Caputo Memorial Award from Wyckoff Medical Center, and the Teaching Excellence Award from Wyckoff Medical Center.